

Listing of the Claims

This listing of claims will replace all prior versions of claims in the application:

1. (currently amended) A penetration composition for non-invasive translocation of at least one effector across a biological barrier, said composition comprising:

- (a) a therapeutically effective amount of said effector;
- (b) a counter ion to the effector; and
- (c) a penetrating peptide

wherein said penetrating peptide is hydrophobized.

2. (original) The penetration composition of claim 1 further comprising a pharmaceutically acceptable excipient, pharmaceutically acceptable carrier, or a combination thereof.

3. (original) The penetration composition of claim 1, wherein said composition is contained within a capsule.

4. (original) The penetration composition of claim 1, wherein said composition is in the form of a tablet.

5. (original) The penetration composition of claim 1, wherein said composition is enteric-coated.

6. (original) The penetration composition of claim 1, wherein said composition is in the form selected from the group consisting of an aqueous dispersion, a suspension and an emulsion.

7. (original) The penetration composition of claim 1, wherein said composition is in the form of a cream.

8. (original) The penetration composition of claim 1, wherein said composition is in the form of an ointment.

9. (original) The penetration composition of claim 1, wherein said composition is in the form of a suppository.

10. (previously presented) The penetration composition of claim 1, wherein said at least one effector is an impermeable molecule.

11. (previously presented) The penetration composition of claim 10, wherein said impermeable molecule is a bioactive molecule used to treat a metabolic disorder.

12-14. (canceled)

15. (currently amended) The penetration composition of claim 11, wherein said bioactive molecule is ~~selected from the group consisting of: insulin; glucagon-like peptide 1 (GLP-1); α -MSH; parathyroid hormone (PTH); growth hormone; and calcitonin.~~

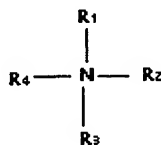
16-24. (canceled)

25. (previously presented) The penetration composition of claim 1, wherein said counter ion is a cationic amphipathic molecule.

26-27. (canceled)

28. (original) The penetration composition of claim 25, wherein said cationic amphipathic molecule is a quaternary amine comprising a hydrophobic moiety.

29. (original) The penetration composition of claim 28, wherein said quaternary amine has the general structure of:



wherein R1, R2, R3 and R4 are alkyl or aryl residues.

30. (original) The penetration composition of claim 29, wherein said quaternary amine is a benzalkonium derivative.

31-38. (canceled)

39. (original) The penetration composition of claim 1, wherein said composition further comprises a polyanionic molecule.

40. (original) The penetration composition of claim 39, wherein said polyanionic molecule is phytic acid.

41. (original) The penetration composition of claim 1, further comprising a surface active agent.

42. (original) The penetration composition of claim 41, wherein said surface active agent is selected from the group consisting of a poloxamer, Solutol HS15, Cremophore and bile acids.

43. (original) The penetration composition of claim 1, wherein said composition is dissolved in an at least partially water soluble solvent.

44. (original) The penetration composition of claim 43, wherein said at least partially water soluble solvent is selected from the group consisting of: n-butanol; isoamyl (=isopentyl) alcohol; iso-butanol; iso-propanol; propanol; ethanol; ter-butanol alcohols; polyols; DMF; DMSO; ethers; amides; esters; and mixtures thereof.

45. (original) The penetration composition of claim 1, wherein any one or more of the components of the composition is lyophilized.

46. (currently amended) The penetration composition of claim 1, wherein said ~~composition further comprises a hydrophobic carrier comprising~~ penetrating peptide is hydrophobized with at least one aliphatic hydrophobic molecule[[s]], ~~wherein said molecules is aliphatic.~~

47. (currently amended) The penetration composition of claim 46, wherein said at least one aliphatic hydrophobic molecule[[s are]] is a fatty acid[[s]].

48-49. (canceled)

50. (original) The penetration composition of claim 1, further comprising at least one protective agent.

51. (currently amended) The penetration composition of claim 50, wherein said protective agent is ~~a protease inhibitor selected from the group consisting of: aprotinin; Bowman-Birk inhibitor; and soybean trypsin inhibitor.~~

52-76. (canceled)

77. (currently amended) The composition of claim 2, wherein the composition further comprises ~~a mixture of at least two substances selected from the group consisting of a non-ionic detergent, a protease inhibitor, and a reducing agent.~~

78. (original) The composition of claim 77, wherein the non-ionic detergent is a poloxamer or Solutol HS15.

79. (original) The composition of claim 78, wherein the poloxamer is pluronic F-68.

80-89. (canceled)

90. (currently amended) A kit for treating diabetes comprising, in one or more containers, a therapeutically ~~or prophylactically~~ effective amount of the composition of claim ~~215~~, and a pharmaceutically acceptable carrier.

91-96. (canceled)

97. (currently amended) An isolated peptide ~~comprising~~ consisting of an the amino acid sequence of SEQ ID NO:24, wherein said peptide is derived from a human neurokinin receptor, and wherein said peptide is characterized by the ability to penetrate biological barriers *in vivo*.

98. (canceled)

99. (original) The penetration composition of claim 1, wherein said penetrating peptide further comprises a chemical modification.

100. (canceled)

101. (original) The penetration composition of claim 99, wherein the chemical modification comprises the attachment of one or more polyethylene glycol residues to the penetrating peptide.

102. (new) The penetration composition of claim 1, wherein the penetrating peptide consists of SEQ ID NO:24.

103. (new) The penetration composition of claim 102, wherein the penetrating peptide is further modified via one or more peptidic bonds, thereby protecting the peptide from gastrointestinal proteolysis.

104. (new) The penetration composition of claim 102, wherein the penetrating peptide further comprises lysine residues interspaced by glycine, alanine, or serine residues added at the C-terminus of said penetrating peptide, and wherein the free amino groups of said lysine residues are acylated.

105. (new) The penetration composition of claim 104, wherein acylation is achieved using a long-chain fatty acid.

106. (new) The penetration composition of claim 105, wherein said long-chain fatty acid is selected from the group consisting of: stearoyl, palmitoyl, oleyl, ricinoleyl, lauroyl, and myristoyl.

107. (new) The penetration composition of claim 105 further comprising N-acetyl cysteine.

108. (new) The penetration composition of claim 107 further comprising tricaprone.